

REMARKS/ARGUMENTS

Claims 38-43 and 45-47 are pending.

Claims 38-43 were examined and rejected.

Claims 38 and 42 are amended. Support for the amendment is found in page 32, lines 29-33; page 24, lines 10-12; and page 15, lines 22-23. No new matter is added.

Claim 44 is cancelled without prejudice.

The Applicants request reconsideration of this application in view of the remarks set forth below.

**Non-compliant amendment**

The Applicants acknowledge and appreciate the Examiner's decision to examine claim 44, which was incorrectly identified as "currently amended" in the Applicant's previous response.

**Request for rejoinder**

Upon allowance of claim 38, the Applicants respectfully request rejoinder of claim 45-47 on the basis that claims 45-47 recite a method of using the composition of claim 38.

**Rejection withdrawn**

The Applicants acknowledge and appreciate the Examiner's decision to withdraw the rejections under 35 U.S.C. 102(e) over *Christenson* (US20030190739), *Geron Corp.* (US 6,599,728) and *Berthelson* (US 6,455,290). The sole remaining rejections are addressed below.

**Rejection of claims under 35 U.S.C. § 102**

Claims 38-40 and 42 is rejected under 35 U.S.C. 102(e) as being allegedly anticipated by *Daly* (US20020037582). The Applicants respectfully traverse this rejection.

As best understood by the Applicants, this rejection is maintained because the Examiner believes that Daly's recombinant cells and recombinant cell extracts inherently contain a Tankyrase H protein that exhibits poly-ADP ribose polymerase activity, and a source of ADP ribose.

Without any intention to acquiesce to the correctness of this rejection and solely to expedite prosecution, the claims have been amended to recite a cell-free composition that contains an isolated Tankyrase H protein that exhibits poly-ADP ribose polymerase activity, and a source of ADP ribose.

The Applicants submit that Daly fails to disclose such a composition and, as such, this rejection should be withdrawn.

In reviewing the argument presented above, the Examiner is requested to consider the MPEP's guidance for establishing rejections based on a theory of inherency. The MPEP § 2112 states that: "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."<sup>1</sup> (emphasis in the original). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing *may* result from a given set of circumstances is also not sufficient.<sup>2</sup>

Since Daly's cell extracts can be made by lysing cells under denaturing conditions (e.g., by boiling the cells or by lysing the cells in a buffer that contains chemical denaturants), Daly's cell extracts do not necessarily contain active Tankyrase H protein, as required by the claims. As such, the Applicants believe that this rejection cannot be supported by a theory of inherency.

In view of the foregoing discussion, the Applicants submit that this rejection should be withdrawn. Withdrawal of this rejection is respectfully requested.

#### **Rejection of claims under 35 U.S.C. § 103**

Claims 41 and 43-44 are rejected under 35 U.S.C. 103 as being unpatentable over *Daly* in view of *Smith*. The Applicants respectfully traverse this rejection.

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<sup>1</sup> MPEP at § 2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

<sup>2</sup> MPEP at § 2112 "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

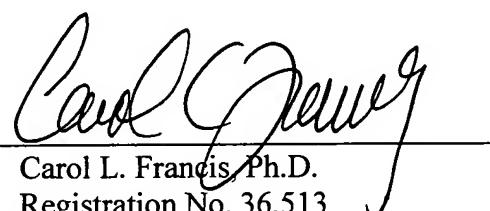
The Applicants submit that *Smith* fails to meet *Daly*'s deficiency sand, as such, *Daly and Smith*, taken in any combination, fail to teach or suggest all of the elements of the rejected claims.

The Applicants submit that these rejections have been adequately addressed. Withdrawal of these rejections is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-010CIP3.

Respectfully submitted,  
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Date: April 5, 2007

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